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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alex C. Toy; John W. Confirmation No. 9361
Forsberg; Mark E.
Schommer; David P.
Olson; William C. Phillips;
Charles R. Lewis, Jr.

Serial No.: 10/693,011

Filed: October 24, 2003 Customer No.: 28863

Examiner: Fernando Aguel

Group Art Unit: 3762

Docket No.: 1023-286US01

Title: CIRCUIT BOARD CONSTRUCTION FOR HANDHELD PROGRAMMER

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Alex C. Toy and John W. Forsberg, declare as follows:

1. We are named inventors in above-referenced Patent Application Serial No. 10/693,011.
2. We are employees of Medtronic, Inc., the Assignee of record for the present application.
3. The above-referenced Patent Application Serial No. 10/693,011 claims priority to Provisional Patent Application Serial No. 60/508,511 filed October 2, 2003.
4. More than one year prior to October 2, 2003, Medtronic, Inc. requested that Benchmark Electronics, Inc. manufacture 222 programmers for a medical device pursuant to assembly drawings shown in Exhibit A. Exhibit A is a two-page document assigned document

number 502814 and relates to a programmer with model number 37741 (“Model 37741 programmer”). On sheet 1, Exhibit A illustrates an assembly view of a Model 37741 programmer for a medical device. On sheet 2, Exhibit A illustrates an assembled view of a Model 37741 programmer for a medical device. Medtronic Inc. confidential and proprietary information has been redacted from Exhibit A.

5. More than one year prior to October 2, 2003, Benchmark Electronics, Inc. manufactured 222 Model 37741 programmers pursuant to the request from Medtronic, Inc.

6. At least 89 of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were used for experimental purposes, as evidenced by Exhibits B-D. Exhibit B is a forty-nine page document assigned document number 288117-70205 and entitled, “Neuro Patient Programmer Platform Electrical DVT Report.” Exhibit C is a one page screen print of an internal electronic document storage and retrieval system at Medtronic, Inc., which indicates that document number 288117-70205 (Exhibit B) was modified on October 7, 2002 and June 28, 2003. Exhibit D is a twenty-nine page document entitled, “DVT Test Data for 288117-70020,” and summarizes the results of tests conducted in May 2002 and June 2002. Medtronic Inc. confidential and proprietary information has been redacted from Exhibits B and D.

7. The remainder of the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. more than one year prior to October 2, 2003 were not used for the tests reflected in Exhibits B and D and were used internally by Medtronic, Inc. employees for development purposes.

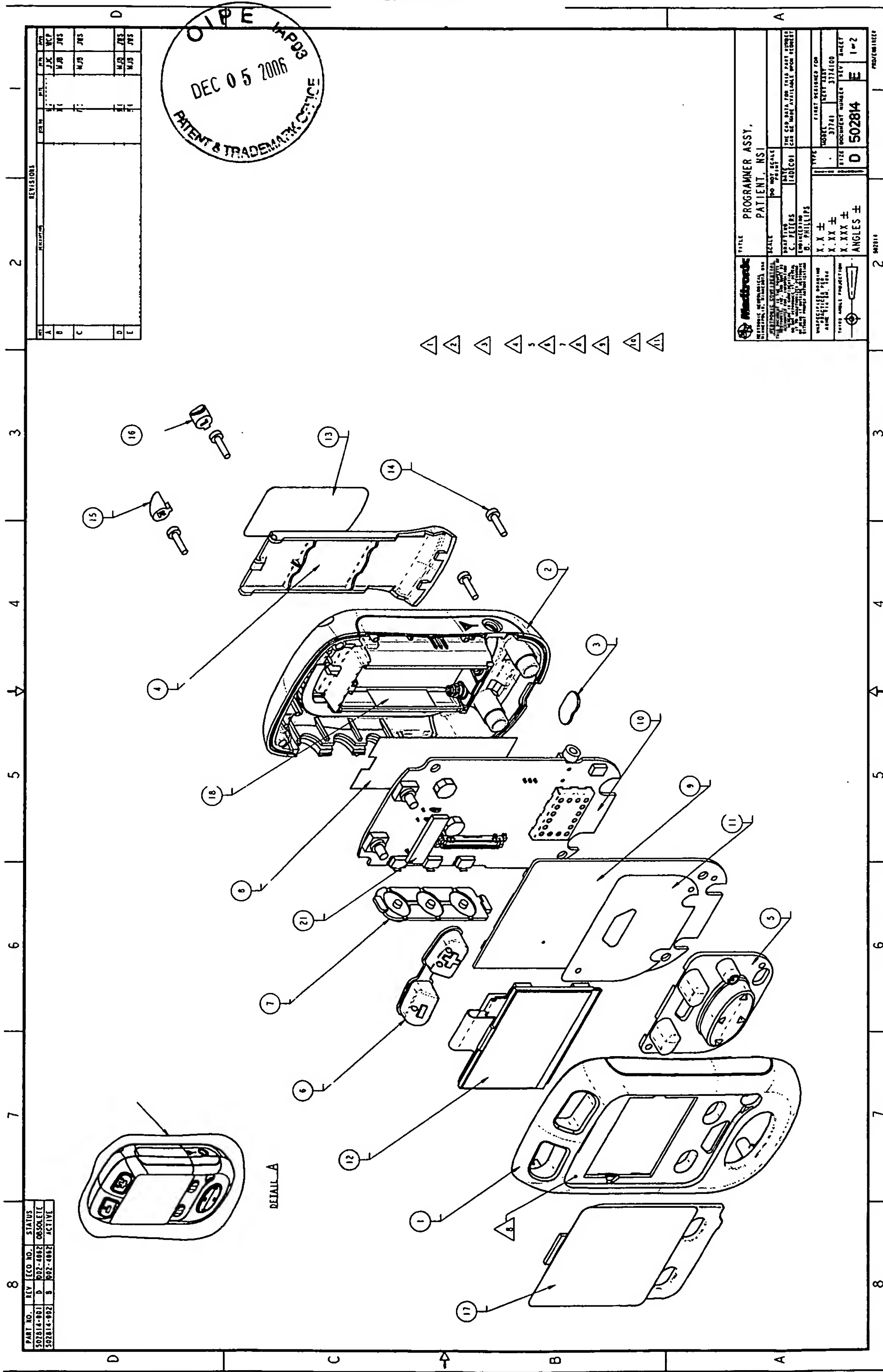
8. In view of this Declaration and the content of Exhibits A-D, it is clear that the 222 Model 37741 programmers manufactured by Benchmark Electronics, Inc. were not “in public use or on sale in this country, more than one year prior to the date of application for patent in the United States” under 35 U.S.C. § 102(b).

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: Oct. 4, 2006 Signed: Alex C. Toy
Alex C. Toy

Date: Oct 4, 2006 Signed: John W. Forsberg
John W. Forsberg

EXHIBIT A



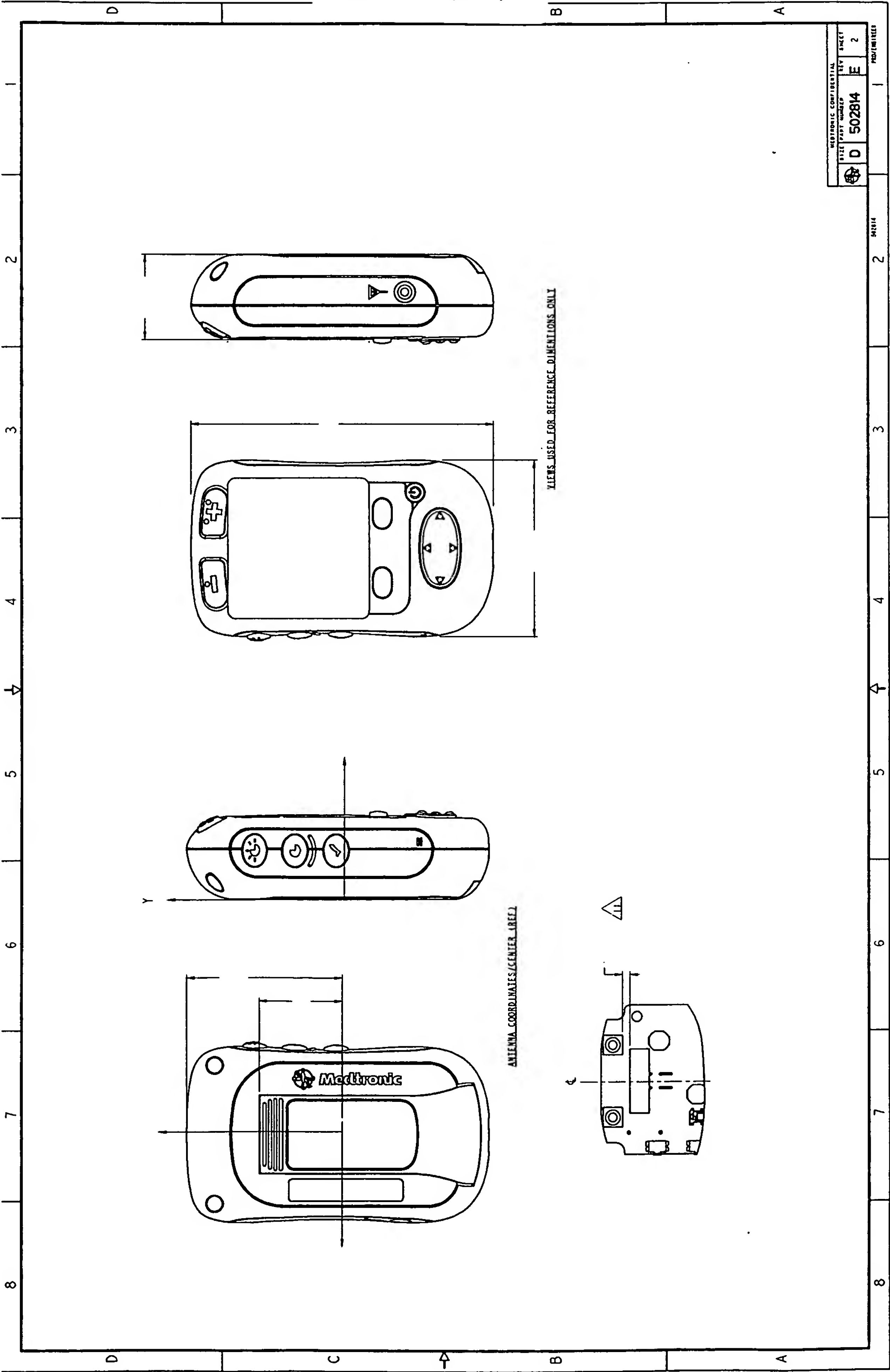
REVISIONS		REV	BY	DATE	DESCRIPTION
1		1	JNS		
2		2	JNS		
3		3	JNS		
4		4	JNS		
5		5	JNS		
6		6	JNS		
7		7	JNS		
8		8	JNS		

DEC 05 2006
PATENT & TRADEMARK OFFICE

TITLE		PROGRAMMER ASSY.	
PATIENT, NSI			
SCALE		1:1	
DRAFTING		C. J. JNS	
C. J. JNS		D. J. JNS	
X. X ±		X. XX ±	
X. XX ±		X. XXX ±	
ANGLES ±		1-2	
FIRST RELEASED FOR		37741	
37741		37741	
D 502814		E 1-2	

PART NO.	REV	ECO NO.	STATUS
502814-001	D	002-002	OBSELETE
502814-002	B	002-002	ACTIVE

EXHIBIT A (cont.)



Test Path #1 from DVT Plan 288117-70020 Section 7.0

DVT Pre-Test Performed to verify operational units.

Serial Number	Buttons			Audio	LCD	Battery contact	Battery Door	Real time			IR	Backlight	Communication	Results
	operational	operational	operational					clock	clock	clock				
NJD000018P		X		X		X		X		X		X		OK
NJD000019P		X		X		X		X		X		X		OK
NJD000020P		X		X		X		X		X		X		OK
NJD000022P		X		X		X		X		X		X		OK
NJD000024P		X		X		X		X		X		X		OK
NJD000025P		X		X		X		X		X		X		OK
NJD000026P		X		X		X		X		X		X		OK
NJD000028P		X		X		X		X		X		X		OK
NJD000031P		X		X		X		X		X		X		OK
NJD000033P		X		X		X		X		X		X		OK
NJD000034P		X		X		X		X		X		X		OK
NJD000035P		X		X		X		X		X		X		OK
NJD000036P		X		X		X		X		X		X		OK
NJD000037P		X		X		X		X		X		X		OK
NJD000077P		X		X		X		X		X		X		OK
NJD000078P		X		X		X		X		X		X		OK
NJD000079P		X		X		X		X		X		X		OK
NJD000080P		X		X		X		X		X		X		OK
NJD000138P		X		X		X		X		X		X		OK
NJD000139P		X		X		X		X		X		X		OK
NJD000140P		X		X		X		X		X		X		OK
NJD000149P		X		X		X		X		X		X		OK

Testing performed by

Date: 23-May-02

EQUIPMENT:

SUMMARY SHEET

PAR# 5365 TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 29 MAY 02 INITIAL VISUAL & ELECTRICAL

SERIAL#	VISUAL	Requestor did functional
NJD000018P	O.K.	X
NJD000019P	O.K.	X
NJD000020P	O.K.	X
NJD000022P	O.K.	X
NJD000024P	O.K.	X
NJD000025P	O.K.	X
NJD000026P	O.K.	X
NJD000028P	O.K.	X
NJD000031P	O.K.	X
NJD000033P	O.K.	X
NJD000034P	O.K.	X
NJD000035P	O.K.	X
NJD000036P	O.K.	X
NJD000037P	O.K.	X
NJD000077P	O.K.	X
NJD000078P	O.K.	X
NJD000079P	O.K.	X
NJD000080P	O.K.	X
NJD000138P	O.K.	X
NJD000139P	O.K.	X
NJD000140P	O.K.	X
NJD000149P	O.K.	X
	3-Jun	

RESULTS: NO ANOMALIES NOTED

SUMMARY SHEET

TEST PLAN: 288117-70020

Patient Programmer for Neuro devices. Life cycle of battery contacts and door, and external antenna jack.
DATE: 19-Jun-02
Subject samples

288117-70020 test

Serial Number	number	Battery			Tested by:	Dimension			Weight		Total Weight
		Door	Battery Contact	External Antenna		Length	Width	Ht.	w/o batteries	2 AA batteries	
	6.3.3	cycles	6.3.4	cycles	6.3.5	cycles	6.3.1		6.3.2	oz.	oz.
NJD000018P											
NJD000019P											
NJD000020P											
NJD000022P											
NJD000024P											
NJD000025P											
NJD000026P											
NJD000028P											
NJD000031P											
NJD000033P											
NJD000034P											
NJD000035P											
NJD000036P											
NJD000037P											
NJD000077P											
NJD000078P											
NJD000079P											
NJD000080P											
NJD000138P											
NJD000139P											
NJD000140P											
NJD000149P											

Average

Test Path #1

DVT Test Data for 288117-70020

Revision 4.0

Std Dev

Dimensions per print 502814

EQUIPMENT:

Exhibit D (cont.)

288117-70183

Page 4 of 29

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices. Storage Temperature paragraph 6.2.2 of test plan.

DATE: 19-Jun-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to low temp. storage of degrees F for hours then degrees F for hours.
Functional test samples post each temperature storage.

Serial #	Functional	Functional
NJD000018P		
NJD000019P		
NJD000020P		
NJD000022P		
NJD000024P		
NJD000025P		
NJD000026P		
NJD000028P		
NJD000031P		
NJD000033P		
NJD000034P		
NJD000035P		
NJD000036P		
NJD000037P		
NJD000077P		
NJD000078P		
NJD000079P		
NJD000080P		
NJD000138P		
NJD000139P		
NJD000140P		
NJD000149P		
Date: Complete	18-Jun	18-Jun 19-Jun 19-Jun

NOTES: A=
B=
C=

Results:

EQUIPMENT:

Exhibit D (cont.)

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices. Operating Temperature paragraph 6.2.1 of test plan.

DATE: 4-Jun-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to Low temp. storage of degrees F for hours then degrees F for hours.

Serial #	Low temp.	Functional	High Temp.	Functional
NJD000018P				
NJD000019P				
NJD000020P				
NJD000022P				
NJD000024P				
NJD000025P				
NJD000026P				
NJD000028P				
NJD000031P				
NJD000033P				
NJD000034P				
NJD000035P				
NJD000036P				
NJD000037P				
NJD000077P				
NJD000078P				
NJD000079P				
NJD000080P				
NJD000138P				
NJD000139P				
NJD000140P				
NJD000149P				
Date: Complete	4-Jun	4-Jun	5-Jun	5-Jun

NOTES: A=

Results:

EQUIPMENT:

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 20-Jun-02 Thermal Shock paragraph 6.2.3 of test plan.

Subject samples to cycles of degrees F, then degrees F, then

Dwell at each temperature for 1 hour. All Functional Testing done per 6.1 except backlight and IR port.

Serial #	Thermal Shock	Functional Testing	Visual
NJD000018P			
NJD000019P			
NJD000020P			
NJD000022P			
NJD000024P			
NJD000025P			
NJD000026P			
NJD000028P			
NJD000031P			
NJD000033P			
NJD000034P			
NJD000035P			
NJD000036P			
NJD000037P			
NJD000077P			
NJD000078P			
NJD000079P			
NJD000080P			
NJD000138P			
NJD000139P			
NJD000140P			
NJD000149P			

NOTES: A=

RESULTS:

EQUIPMENT:

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 21-Jun-02

Chemical Resistance paragraph 6.2.7 of test plan.

Subject samples to

	Chemical	Visual
Serial #	Testing	
NJD000018P		
NJD000019P		
NJD000020P		
NJD000022P		
NJD000024P		
NJD000025P		
NJD000026P		
NJD000028P		
NJD000031P		
NJD000033P		
NJD000034P		
NJD000035P		
NJD000036P		
NJD000037P		
NJD000077P		
NJD000078P		
NJD000079P		
NJD000080P		
NJD000138P		
NJD000139P		
NJD000140P		
NJD000149P		

RESULTS:

EQUIPMENT:

Test Path #2 from DVT Plan 288117-70020 Section 7.0

DVT Pre-Test Performed to verify operational units.

Serial Number	Buttons			Battery		Battery		Real time		IR		Backlight		Communication		Results
	operational	Audio	LCD	contact	Door	clock										
NJD000109P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000110P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000111P	x	x	x	x	x	x	x	x						x		OK
NJD000113P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000114P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000116P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000119P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000120P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000121P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000122P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000123P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000124P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000126P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000127P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000128P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000129P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000130P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000131P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000133P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000134P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000136P	x	x	x	x	x	x	x	x	x	x		x		x		OK
NJD000137P	x	x	x	x	x	x	x	x	x	x		x		x		OK

Testing performed by

Date:

23-May-02

EQUIPMENT: I

I

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 29 MAY 02

INITIAL VISUAL & ELECTRICAL

SERIAL#	VISUAL	Requestor did functional
NJD000109P	O.K.	X
NJD000110P	O.K.	X
NJD000111P	O.K.	X
NJD000113P	O.K.	X
NJD000114P	O.K.	X
NJD000116P	O.K.	X
NJD000119P	O.K.	X
NJD000120P	O.K.	X
NJD000121P	O.K.	X
NJD000122P	O.K.	X
NJD000123P	O.K.	X
NJD000124P	O.K.	X
NJD000126P	O.K.	X
NJD000127P	O.K.	X
NJD000128P	O.K.	X
NJD000129P	O.K.	X
NJD000130P	O.K.	X
NJD000131P	O.K.	X
NJD000133P	O.K.	X
NJD000134P	O.K.	X
NJD000136P	O.K.	X
NJD000137P	O.K.	X
	29-May	

RESULTS:

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

Broad Band Random Vibration paragraph 6.2.4 of test plan.

DATE:

4-Jun-02

All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to

SERIAL#	Back down	Visual	R. side dow	Visual	Top up	Visual	Functional	Observations
NJD000109P								
NJD000110P								
NJD000111P								
NJD000113P								
NJD000114P								
NJD000116P								
NJD000119P								
NJD000120P								
NJD000121P								
NJD000122P								
NJD000123P								
NJD000124P								
NJD000126P								
NJD000127P								
NJD000128P								
NJD000129P								
NJD000130P								
NJD000131P								
NJD000133P								
NJD000134P								
NJD000136P								
NJD000137P								
Date Completed	7-Jun	7-Jun	7-Jun	7-Jun	7-Jun	7-Jun	13-Jun	

NOTES:

A=

B=

C=

RESULTS:

EQUIPMENT:

SUMMARY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH: ROY POPE

Patient Programmer for Neuro devices.

Mechanical Shock paragraph 6.2.5 of test plan.

DATE: 20-Jun-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to

SERIAL#	Front	Back	Top	Bottom	Left side	Right side	Testing
NJD000109P							
NJD000110P							
NJD000111P							
NJD000113P							
NJD000114P							
NJD000116P							
NJD000119P							
NJD000120P							
NJD000121P							
NJD000122P							
NJD000123P							
NJD000124P							
NJD000126P							
NJD000127P							
NJD000128P							
NJD000129P							
NJD000130P							
NJD000131P							
NJD000133P							
NJD000134P							
NJD000136P							
NJD000137P							

NOTES: A=
B=

RESULTS:

EQUIPMENT:

Test Path #3 from DVT Plan 288117-70020 Section 7.0

DVT Pre-Test Performed to verify operational units.

Serial Number	Buttons		Audio	LCD	Battery		Door	Real time clock	IR	Backlight	Communication	Results
	operational				contact							
NJD000081P	x		x	x	x		x	x	x	x	x	OK
NJD000082P	x		x	x	x		x	x	x	x	x	OK
NJD000083P	x		x	x	x		x	x	x	x	x	OK
NJD000084P	x		x	x	x		x	x	x	x	x	OK
NJD000086P	x		x	x	x		x	x	x	x	x	OK
NJD000087P	x		x	x	x		x	x	x	x	x	OK
NJD000089P	x		x	x	x		x	x	x	x	x	OK
NJD000092P	x		x	x	x		x	x	x	x	x	OK
NJD000093P	x		x	x	x		x	x	x	x	x	OK
NJD000094P	x		x	x	x		x	x	x	x	x	OK
NJD000096P	x		x	x	x		x	x	x	x	x	OK
NJD000097P	x		x	x	x		x	x	x	x	x	OK
NJD000098P	x		x	x	x		x	x	x	x	x	OK
NJD000099P	x		x	x	x		x	x	x	x	x	OK
NJD000100P	x		x	x	x		x	x	x	x	x	OK
NJD000101P	x		x	x	x		x	x	x	x	x	OK
NJD000102P	x		x	x	x		x	x	x	x	x	OK
NJD000103P	x		x	x	x		x	x	x	x	x	OK
NJD000104P	x		x	x	x		x	x	x	x	x	OK
NJD000106P	x		x	x	x		x	x	x	x	x	OK
NJD000107P	x		x	x	x		x	x	x	x	x	OK
NJD000108P	x		x	x	x		x	x	x	x	x	OK

Testing performed by

Date: 23-May-02

EQUIPMENT: I

I

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 29 MAY 02

INITIAL VISUAL & ELECTRICAL

SERIAL#	VISUAL	Requestor did functional
NJD000081P	O.K.	X
NJD000082P	O.K.	X
NJD000083P	O.K.	X
NJD000084P	O.K.	X
NJD000086P	O.K.	X
NJD000087P	O.K.	X
NJD000089P	O.K.	X
NJD000092P	O.K.	X
NJD000093P	O.K.	X
NJD000094P	O.K.	X
NJD000096P	O.K.	X
NJD000097P	O.K.	X
NJD000098P	O.K.	X
NJD000099P	O.K.	X
NJD000100P	O.K.	X
NJD000101P	O.K.	X
NJD000102P	O.K.	X
NJD000103P	O.K.	X
NJD000104P	O.K.	X
NJD000106P	O.K.	X
NJD000107P	O.K.	X
NJD000108P	O.K.	X
Date: Complete	29-May	

RESULTS: NO ANOMALIES NOTED

SUMMERY SHEET

PAR# 5365

TEST PLAN: 288117-70020

TECH:

Patient Programmer for Neuro devices.

DATE: 29-May-02 All Functional Testing done per 6.1 except backlight and IR port.

Subject samples to degrees F and RH for days. Test samples per request days.

SERIAL#						
NJD000081P						
NJD000082P						
NJD000083P						
NJD000084P						
NJD000086P						
NJD000087P						
NJD000089P						
NJD000092P						
NJD000093P						
NJD000094P						
NJD000096P						
NJD000097P						
NJD000098P						
NJD000099P						
NJD000100P						
NJD000101P						
NJD000102P						
NJD000103P						
NJD000104P						
NJD000106P						
NJD000107P						
NJD000108P						
Date: Complete	3-Jun	3-Jun	4-Jun	4-Jun	19-Jun	19-Jun

NOTES:

- A=
- B=
- C=
- D=

RESULTS:

- E=
- F=
- G=
- H=

EQUIPMENT: -

I=

Exhibit D (cont.)

Section 6.3.6 Button Endurance - Specification for KSS321G, used for
... buttons (
Life Cycle data show life expectancy of

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.8 Flamability - Both top and bottom housings are made from

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 - Button Endurance - Specification for KSC621- Used for top buttons (Life Cycle data show life expectancy

.....

.....

...

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

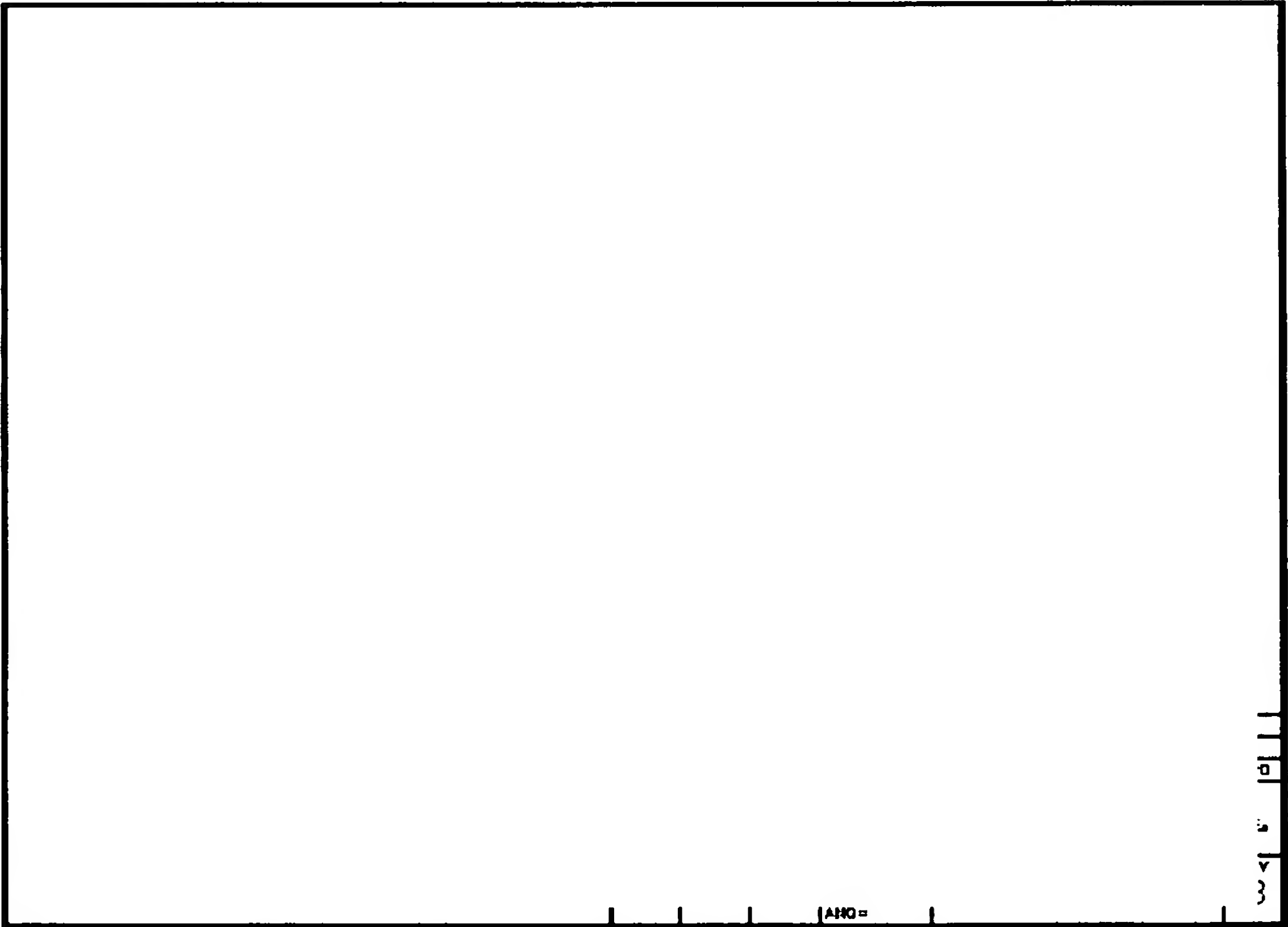
A-21

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.6 - Button Endurance - Specification for F
Used for
Life Cycle data show
life expectancy of



Blank Page



Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

Section 6.3.7 Scratch resistance -

—



Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

—

Exhibit D (cont.)

Other Data

DVT Test Data for 288117-70020

Revision 4.0

—

wdkSpace - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back •

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EXHIBIT B

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Revision History:


Revision	Comments
1.0	Initial release for routing

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1 INTRODUCTION

This document is the electrical Design Verification Test (DVT) Report for the 37741 Patient Programmer Platform.

1.1 Purpose

The purpose of this report is to document the results of test plan .

1.2 Scope


This report applies only to design verification testing of the 37741 Patient Programmer Platform.

1.3 Document Overview

This document is organized as follows:

- Section 2 contains references and definitions.
- Section 3 contains a table with the list of tests, software revisions, sample sizes, and test results.
- Section 4 contains the results of the electrical design verification tests.

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2 REFERENCES AND DEFINITIONS

This section identifies internal and external reference documents that augment the information provided in this document. It also defines terms, acronyms, and abbreviations used within the document.

2.1 Internal Medtronic References

Number	Name
120275	
215387	
288117-70040	
288117-70044	
288117-70029	
503011001	
288117-70200	

Note: Document revisions referenced in DVT Plan.

2.2 External References

Reference the PEM Electrical Specification for external specification standards.

2.3 Definitions, Acronyms, and Abbreviations

ARB: Arbitrary Waveform Generator

ARB equipment: One or more arbitrary waveform generators, used alone or in conjunction to generate sophisticated waveforms.

DUT: Device Under Test

DVT: Design Verification Test

DVT Console: The test console needed to perform the tests specified herein.

ES: Electrical Specification #120275


GPB: General Purpose Interface Bus

PEM: Patient Electronic Module

PP: Patient Programmer

POR: Power On Reset

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3 Test Results Summary


Table 1 summarizes the results of all electrical design verification testing. Section 4 details each test setup, criteria, and results.

- Test data is stored as 288117-70200.
- Table 1 indicates test name, sample size, DUT software revision, Test Script Software revision, test path, and results.
- Test paths are shown in section 3.1.

Table 1

Test Name	Sample Size	DUT Software Revision	Script Software Test Revision	Test Path	Results
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	22				PASS
	1				PASS

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3.1 Test Paths

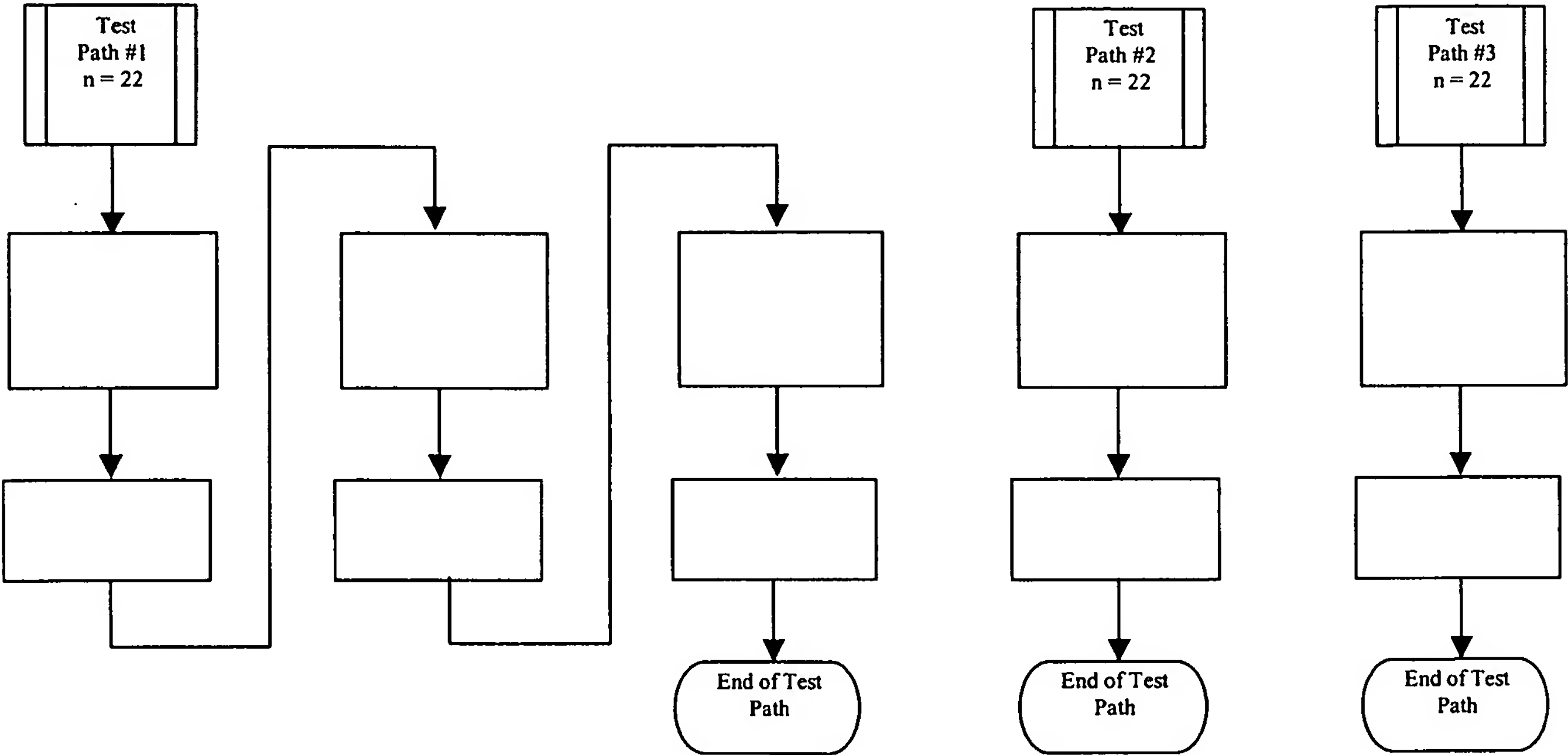



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4 ELECTRICAL TESTS

This section specifies electrical tests performed on the 37741 Patient Programmer Platform.

4.1 Power Source Tests

4.1.1 Current Drain Test

4.1.1.1 Objective

To verify the current drain meets the requirements specified in the *Power Source* section of the PEM Electrical Specification.

4.1.1.2 Method and Equipment

4.1.1.3 Test Cases

There are 2 test cases for transmit using all combinations of test values below:

Parameter	Test Values	Units

The

There are test cases using all combinations of test values below:

Parameter	Test Values	Units


There are test cases using two combinations of test values below:

Parameter	Test Values	Units

There are total test cases.

4.1.1.4 Acceptance Criteria

EXHIBIT B (cont.)

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Operating Condition (Ref.)	Antenna	Duty Cycle (%)	Current Drain (mA) MAX		
			V	V	V
Row A	INT				
Row B	INT				
Row C	INT				
Row D	INT				
Row E	INT				
Row F	INT				
Row G	INT				
Row H	EXT				
Row I	INT				
Row J	INT				

Note 1:

4.1.1.5 Test Setup


- 1.
- 2.
- 3.
- 4.

4.1.1.6 Test Procedure

- 1.
- 2.

- 3.
- 4.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 9 of 49
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4.1.1.7 RESULTS **PASS**
All devices met the acceptance criteria.

Operating Condition	Current Drain (mA) MAX																	
Row	Spec	Min	Max	Mean	Std Dev		Spec	Min	Max	Mean	Std Dev		Spec	Min	Max	Mean	Std Dev	
A																		
B																		
C																		
D																		
E																		
F																		
G																		
H																		
I																		
J																		


4.1.2 **Supply Voltage Range Test**

4.1.2.1 Objective
To verify the supply voltage range meets the requirements specified in the *Power Source* section of the PEM Electrical Specification.

4.1.2.2 Method and Equipment

4.1.2.3 Test Cases

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 10 of 49
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Parameter	Test Values	Units

The
There is test case without transmit:

Parameter	Test Values	Units

4.1.2.4 Acceptance Criteria

Operating Condition	Antenna	H-Bridge Drive Duty Cycle (%)	Min operating voltage (V)


4.1.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.

4.1.2.6 Test Procedure

- 1.
- 2.
- 3.

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 11 of 49
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4.1.2.7 RESULTS **PASS**

All devices met the acceptance criteria.

Operating Condition	Antenna	Supply Voltage Range (Volts)			
		Min	Max	Avg	Std Dev
—	—	—	—	—	—
—	—	—	—	—	—

4.2 Input/Output Connections Tests

4.2.1 Keypad Interface Test

4.2.1.1 Objective

To verify the keypad interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.1.2 Method and Equipment

4.2.1.3 Test Cases

Parameter	Test Values	Units
—	—	—


4.2.1.4 Acceptance Criteria

4.2.1.5 Test Setup

- 1.
- 2.
- 3.

4.2.1.6 Test Procedure

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 12 of 49
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3.

4.2.1.7 RESULTS **PASS**

All devices met the acceptance criteria.

Tests	Keypad Interface (pass/fail)		
	Pass	Pass	Pass
	Pass	Pass	Pass

4.2.2 **Display Interface Test**

4.2.2.1 Objective

To verify the display interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.


4.2.2.2 Method and Equipment

4.2.2.3 Test Cases

There are test cases using combinations of the test values below:

Parameter	Test Values	Units

EXHIBIT B (cont.)

 Medtronic	<i>Neurological</i>	Document Number 288117-70205	Rev/Version 1.0	Sht 13 of 49
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4.2.2.4 Acceptance Criteria

Test Parameters				Requirements			

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4.2.3 External Antenna Interface Test

4.2.3.1 Objective

To verify the external antenna interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.3.2 Method and Equipment

4.2.3.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

4.2.3.4 Acceptance Criteria


- When an external antenna is connected, there should be no downlink from the internal antenna.
- When an external antenna is connected, the uP should detect that the antenna is connected.

External Antenna					Yes/No
	Min	Max	Min	Max	

4.2.3.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

EXHIBIT B (cont.)

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4.2.3.6 Test Procedure

1.

2.


3.

4.

4.2.3.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

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Test Configuration	Test
	A
	B

Test	External Antenna Interface (A/m)														
	Min	Max	Mean	Std dev		Min	Max	Mean	Std dev		Min	Max	Mean	Std dev	
A															
B															

4.2.4 Infrared Port Interface Test

4.2.4.1 Objective

To verify the infrared port interface meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification. [PTPROG_PEMT-0006:~]

4.2.4.2 Method and Equipment

4.2.4.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

4.2.4.4 Acceptance Criteria

All	All	None

4.2.4.5 Test Setup

- 1.
- 2.

EXHIBIT B (cont.)



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3.

4.2.4.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.2.4.7 RESULTS **PASS**

All devices met the acceptance criteria.

Voltage (V)	Infrared (pass/fail)								
	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

4.2.5 **Audio Transducer Test**

4.2.5.1 Objective


To verify the audio transducer meets the requirements specified in the *Input/Output Connections* section of the PEM Electrical Specification.

4.2.5.2 Method and Equipment

4.2.5.3 Test Cases

There are test cases using all combinations of test values below:

EXHIBIT B (cont.)

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Parameter	Test Values	Units

4.2.5.4 Acceptance Criteria

4.2.5.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.2.5.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.2.5.7 RESULTS **PASS**


All devices met the acceptance criteria.

	Audio Transducer (dB SPL)														
	Min	Max	Mean	Std dev		Min	Max	Mean	Std dev		Min	Max	Mean	Std dev	

4.2.6 **Manufacturing/Test Interface Test**

Manufacturing requirements defined in Test Specification, Patient Programmer, 215387.

EXHIBIT B (cont.)

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4.3 Internal Resources Tests

4.3.1 Memory Test

4.3.1.1 Objective

To verify the internal memory resources meet the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.1.2 Method and Equipment

4.3.1.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

4.3.1.4 Acceptance Criteria

All	Pass

4.3.1.5 Test Setup

- 1.
- 2.
- 3.

4.3.1.6 Test Procedure


- 1.
- 2.
- 3.
- 4.

4.3.1.7 RESULTS **PASS**

All devices met the acceptance criteria.

Test	Memory (pass/fail)		
	Pass	Pass	Pass
	Pass	Pass	Pass
	Pass	Pass	Pass

EXHIBIT B (cont.)

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4.3.2 Real-Time Clock Backup Test

4.3.2.1 Objective

To verify the real-time clock backup meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.2.2 Method and Equipment

4.3.2.3 Test Cases

There is one test case below:

Parameter	Test Value	Units

4.3.2.4 Acceptance Criteria

Test Case	Min Time w/o power (min)

4.3.2.5 Test Setup

- 1.
- 2.
- 3.


4.3.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.

4.3.2.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

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Test	Real-Time Backup (pass/fail)		
	Pass	Pass	Pass

4.3.3 Real-Time Clock Accuracy Test

4.3.3.1 Objective

To verify the real-time clock accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

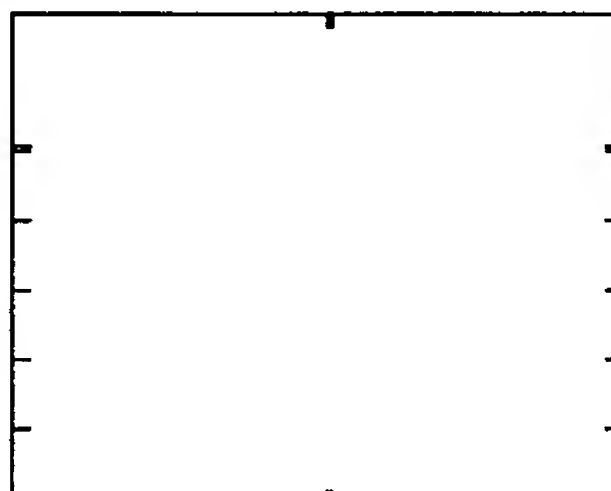
4.3.3.2 Method and Equipment

4.3.3.3 Test Cases

There are test cases (actually measurement points) using all combinations of test values below:

Parameter	Test Value	Units

4.3.3.4 Acceptance Criteria



4.3.3.5 Test Setup

- 1.
- 2.


4.3.3.6 Test Procedure

- 1.
- 2.

4.3.3.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

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	Real Time Clock Accuracy (seconds)				

4.3.4 A/D Measurements Test

4.3.4.1 Objective

To verify the A/D measurement accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.4.2 Method and Equipment

4.3.4.3 Test Cases

There are test cases using the test values below:

Parameter	Test Values	Units


4.3.4.4 Acceptance Criteria

A/D Voltage	Test Value	Max Error (%)

4.3.4.5 Test Setup

- 1.
- 2.
- 3.
- 4.

EXHIBIT B (cont.)

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5.

4.3.4.6 Test Procedure

1.

2.


3.

4.

4.3.4.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

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[illegible]

4.3.5 D/A Control Voltages Test

4.3.5.1 Objective


To verify the D/A accuracy meets the requirements specified in the *Internal Resources* section of the PEM Electrical Specification.

4.3.5.2 Method and Equipment

4.3.5.3 Test Cases

There are test cases using all combinations of test values below:

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Parameter	Test Value	Units

4.3.5.4 Acceptance Criteria

D/A Voltage	Measurement point	Max % Error

4.3.5.5 Test Setup

- 1.
- 2.
- 3.
- 4.

4.3.5.6 Test Procedure

- 1.
- 2.
- 3.

4.3.5.7 RESULTS PASS

All devices met the acceptance criteria.

[illegible]


4.4 Transmit Telemetry (Downlink) Tests

4.4.1 Magnetic Field Intensity Test

4.4.1.1 Objective

To verify downlink magnetic field intensity meets the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.

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4.4.1.2 Method and Equipment

4.4.1.3 Test Cases

There are test cases at kHz using all combinations of test values below:

4.4.1.4 Acceptance Criteria


4.4.1.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.4.1.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

EXHIBIT B (cont.)

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5.

4.4.1.7 RESULTS PASS

All devices met the acceptance criteria.

Magnetic Field Intensity (A/m)

4.4.2 Burst Characteristics Test

4.4.2.1 Objective

To verify downlink burst characteristics of width, rise time, fall time, frequency, and overshoot meet the requirements specified in the *Transmit Telemetry (Downlink)* section of the PEM Electrical Specification.


4.4.2.2 Method and Equipment

4.4.2.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

EXHIBIT B (cont.)

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4.4.2.4 Acceptance Criteria

A blank coordinate grid with x and y axes ranging from -10 to 10. The grid lines are spaced at intervals of 1 unit. The x-axis is labeled 'x' and the y-axis is labeled 'y'.

4.4.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.

- 5.

4.4.2.6 Test Procedure


- 1.
- 2.

3.
4.
5.


4.4.2.7 RESULTS PASS

All devices met the acceptance criteria.

7

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[illegible]

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4.5 Receive Telemetry (Uplink) Tests

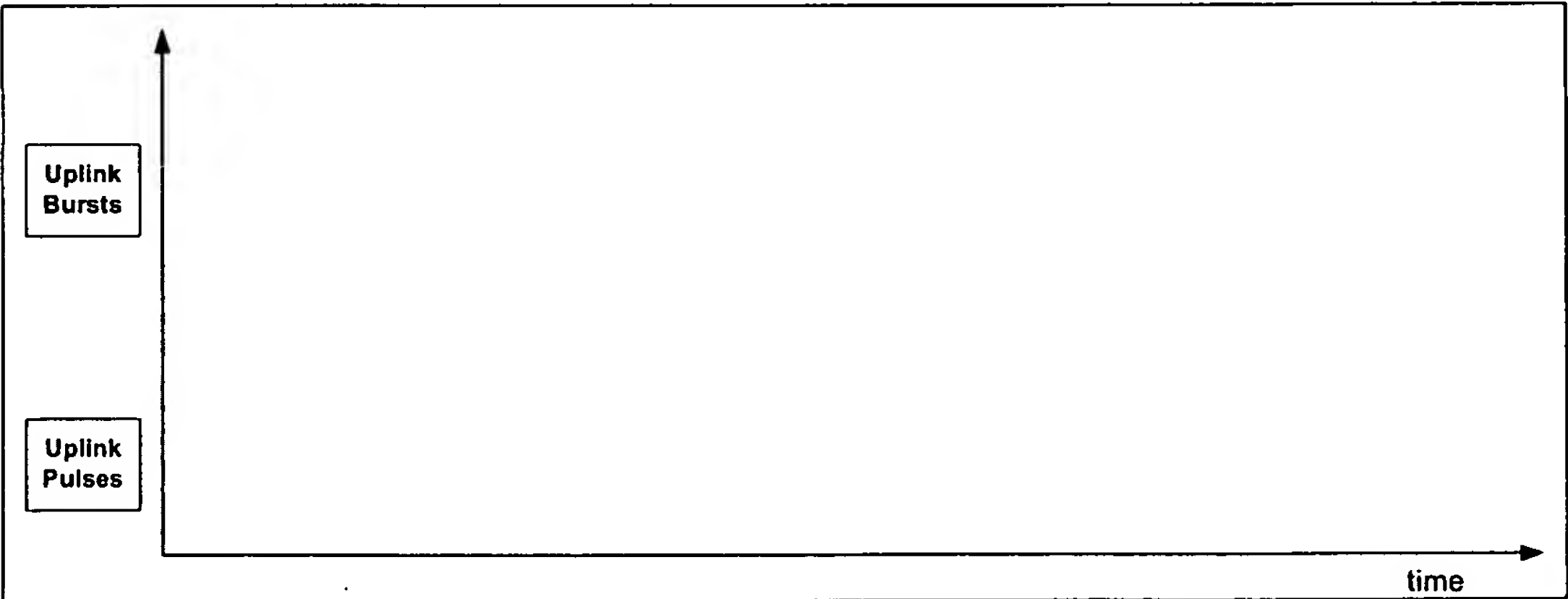
4.5.1 Detection Threshold Test

4.5.1.1 Objective

To verify uplink detection threshold (i.e. receiver sensitivity) meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.1.2 Method and Equipment

Figure 1: Example Uplink Detection Threshold Test Waveforms




4.5.1.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

The supply voltage is 2.5 V.

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4.5.1.4 Acceptance Criteria

Antenna	Telemetry Type	Detection Onset (Uplink dB)	Detection Threshold (Uplink dB)	Maximum Input Level (Uplink dB)
		Max	Max	Max

4.5.1.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.

4.5.1.6 Test Procedure


- 1.
- 2.
- 3.
- 4.

4.5.1.7 RESULTS PASS

All devices met the acceptance criteria.

[illegible]

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Antenna	Telemetry	Maximum Input Level (pass/fail)		
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass
		Pass	Pass	Pass

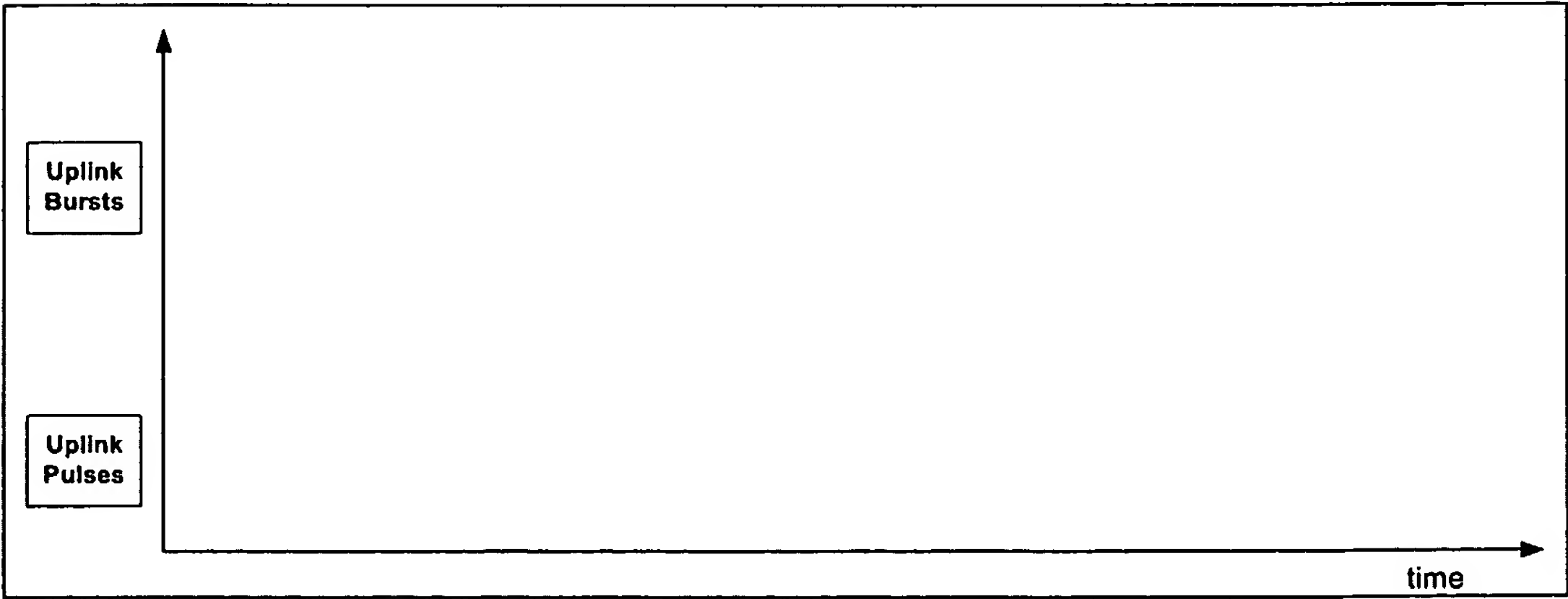
4.5.2 Detection Margin Test

4.5.2.1 Objective

To verify uplink detection margin meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.2.2 Method and Equipment


Figure 2: Example Uplink Detection Margin Test Waveforms



4.5.2.3 Test Cases

There are test cases using all combinations of test values below:

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Parameter	Test Values	Units

4.5.2.4 Acceptance Criteria

Telemetry Type	Data Bursts	Amplitude A1	Antenna	Detection Margin (Uplink dB)	
				Min	Max

4.5.2.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.


4.5.2.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.5.2.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

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[illegible]

4.5.3 Noise Immunity Test

4.5.3.1 Objective

To verify uplink noise immunity meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.3.2 Method and Equipment


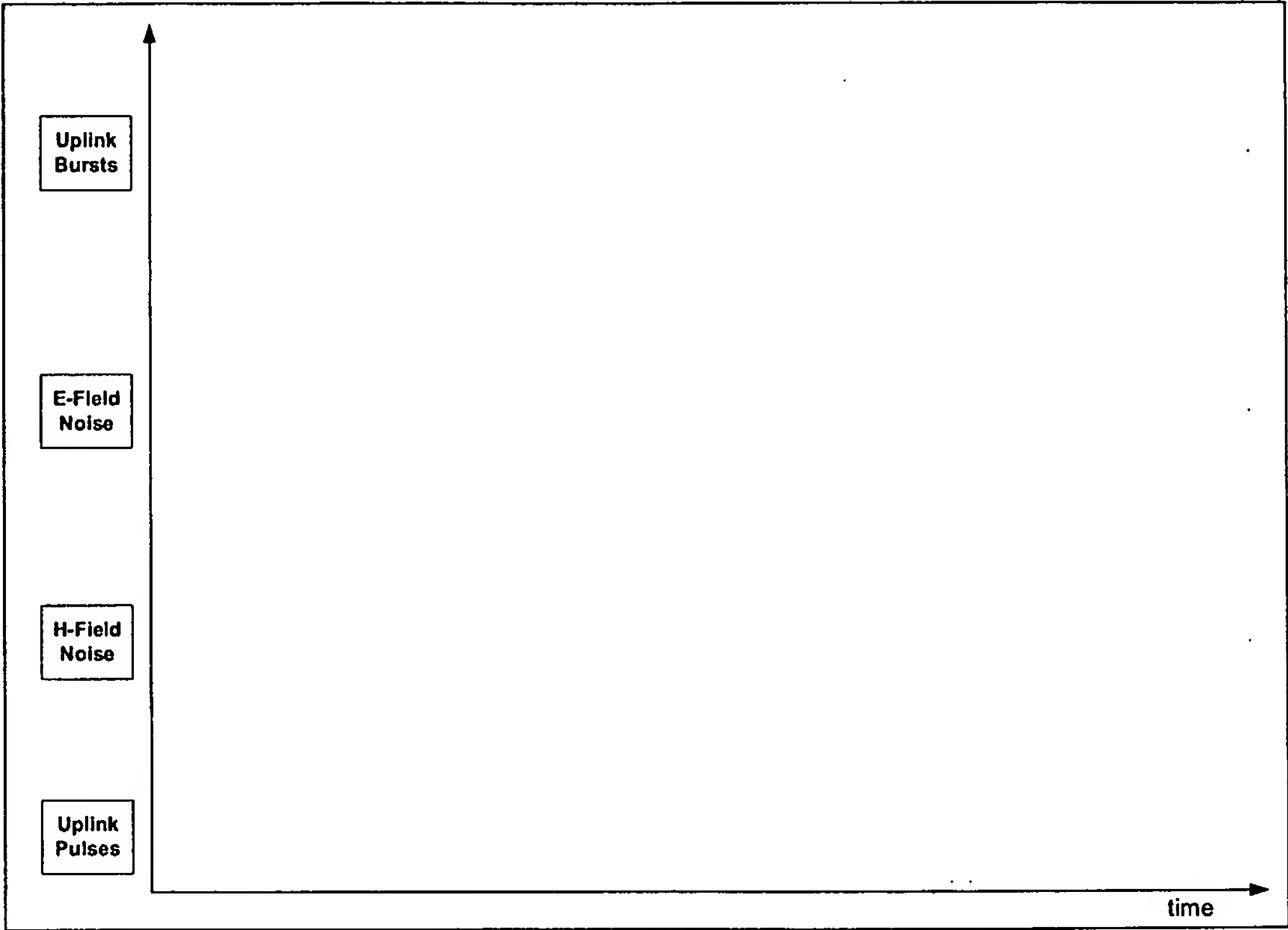
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Figure 3: Example Uplink Noise Immunity Test Waveforms




4.5.3.3 Test Cases

There are test cases using all combinations of test values below:

Parameter	Test Values	Units

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4.5.3.4 Acceptance Criteria

Telemetry Type	Uplink Level A1 (dB)	Antenna	Min E-Noise Immunity (dB)	Min H-Noise Immunity (dB)

4.5.3.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.


4.5.3.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.

4.5.3.7 RESULTS **PASS**

All devices met the acceptance criteria.

EXHIBIT B (cont.)

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[illegible]


4.5.4 Signal Distortion Test

4.5.4.1 Objective

To verify uplink signal distortion meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.4.2 Method and Equipment

EXHIBIT B (cont.)

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4.5.4.3 Test Cases

Parameter	Test Values	Units

There are test cases for Tel A, and test cases for Tel N.

4.5.4.4 Acceptance Criteria

Telemetry Type	Uplink Level A1 (dB)	Antenna	Interval Distortion (µS)	Active/Idle Distortion (µS)

4.5.4.5 Test Setup

- 1.
- 2.
- 3.
- 4.
- 5.


4.5.4.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.5.4.7 RESULTS **PASS**


All devices met the acceptance criteria.

EXHIBIT B (cont.)

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[illegible][illegible]

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[illegible]

4.5.5 Turnaround Time Test

4.5.5.1 Objective

To verify uplink turnaround time meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.


4.5.5.2 Method and Equipment

4.5.5.3 Test Cases

There are $2^4 = 16$ test cases using all combinations of test values below:

Parameter	Test Values	Units

EXHIBIT B (cont.)

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4.5.5.4 Acceptance Criteria

Supply Voltage	H-Bridge Drive Duty Cycle	Turnaround Time (mS)

4.5.5.5 Test Setup

- 1.
- 2.
- 3.

4.5.5.6 Test Procedure

- 1.
- 2.
- 3.
- 4.

4.5.5.7 RESULTS **PASS**

All devices met the acceptance criteria.

Test	Turnaround Time (pass/fail)


4.5.6 **Hold Drift Test**

4.5.6.1 Objective

To verify the hold drift meets the requirements specified in the *Receive Telemetry (Uplink)* section of the PEM Electrical Specification.

4.5.6.2 Method and Equipment

EXHIBIT B (cont.)

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4.5.6.3 Test Cases

There is test case:

Parameter	Uplink Level	Units

4.5.6.4 Acceptance Criteria

Time after hold circuit enabled	Max Hold Drift


4.5.6.5 Test Setup

- 1.
- 2.
- 3.

4.5.6.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10

EXHIBIT B (cont.)

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4.5.6.7 RESULTS **PASS**

All devices met the acceptance criteria.

Hold Drift (mV)
<div style="border: 1px solid black; height: 70px; width: 100%;"></div>

4.5.7 **New-Battery FET Test**

4.5.7.1 Objective

To verify that enabling the new-battery FET circuit reduces the receiver noise floor (ambient RF energy detected by the receiver circuit) when new batteries are used.

4.5.7.2 Method and Equipment

4.5.7.3 Test Cases

There is test case:

Parameter	Uplink Level	Units


4.5.7.4 Acceptance Criteria

Supply Voltage	New-Battery FET	RSSI Peak

4.5.7.5 Test Setup

- 1.
- 2.
- 3.

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4.5.7.6 Test Procedure

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

4.5.7.7 RESULTS **PASS**

All devices met the acceptance criteria.

	New-Battery FET (mV)											
	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev	Min	Max	Mean	Std dev

4.6 Telemetry Performance Tests


4.6.1 Telemetry Map Area at a Fixed Distance Test

4.6.1.1 Objective

To verify telemetry performance in terms of map area at a fixed distance meets the requirements specified in the *Telemetry Performance* section of the PEM Electrical Specification.

4.6.1.2 Method and Equipment

EXHIBIT B (cont.)

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4.6.1.3 Test Cases

Parameter	Test Values	Units

There are test cases.

4.6.1.4 Acceptance Criteria

IPG	Antenna	Map Area @ 5cm

4.6.1.5 Test Setup


- 1.
- 2.

4.6.1.6 Test Procedure

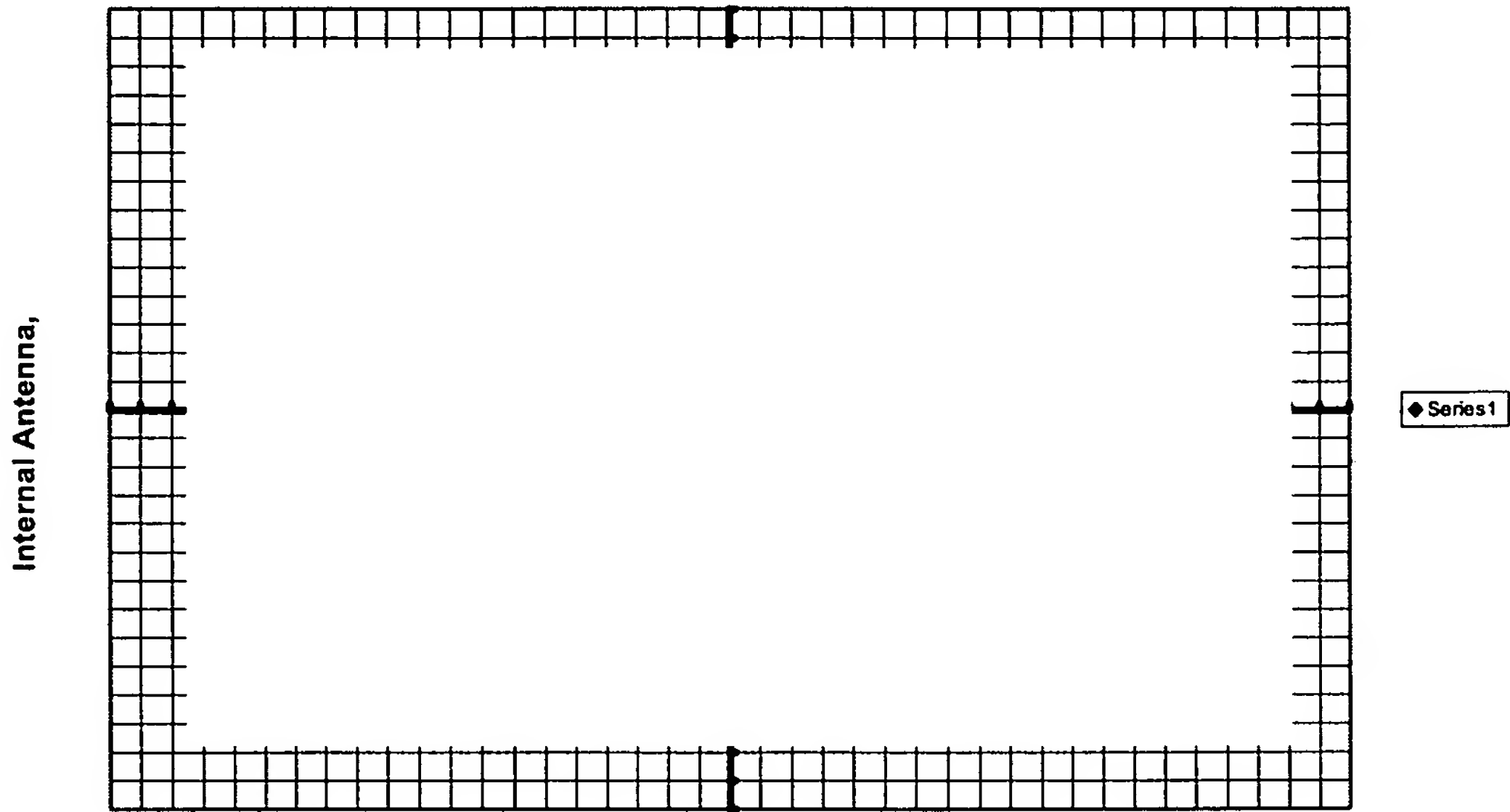
- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

4.6.1.7 RESULTS **PASS**

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4.6.1.7.1 Internal Antenna Map @



4.6.1.7.2 Internal Antenna @

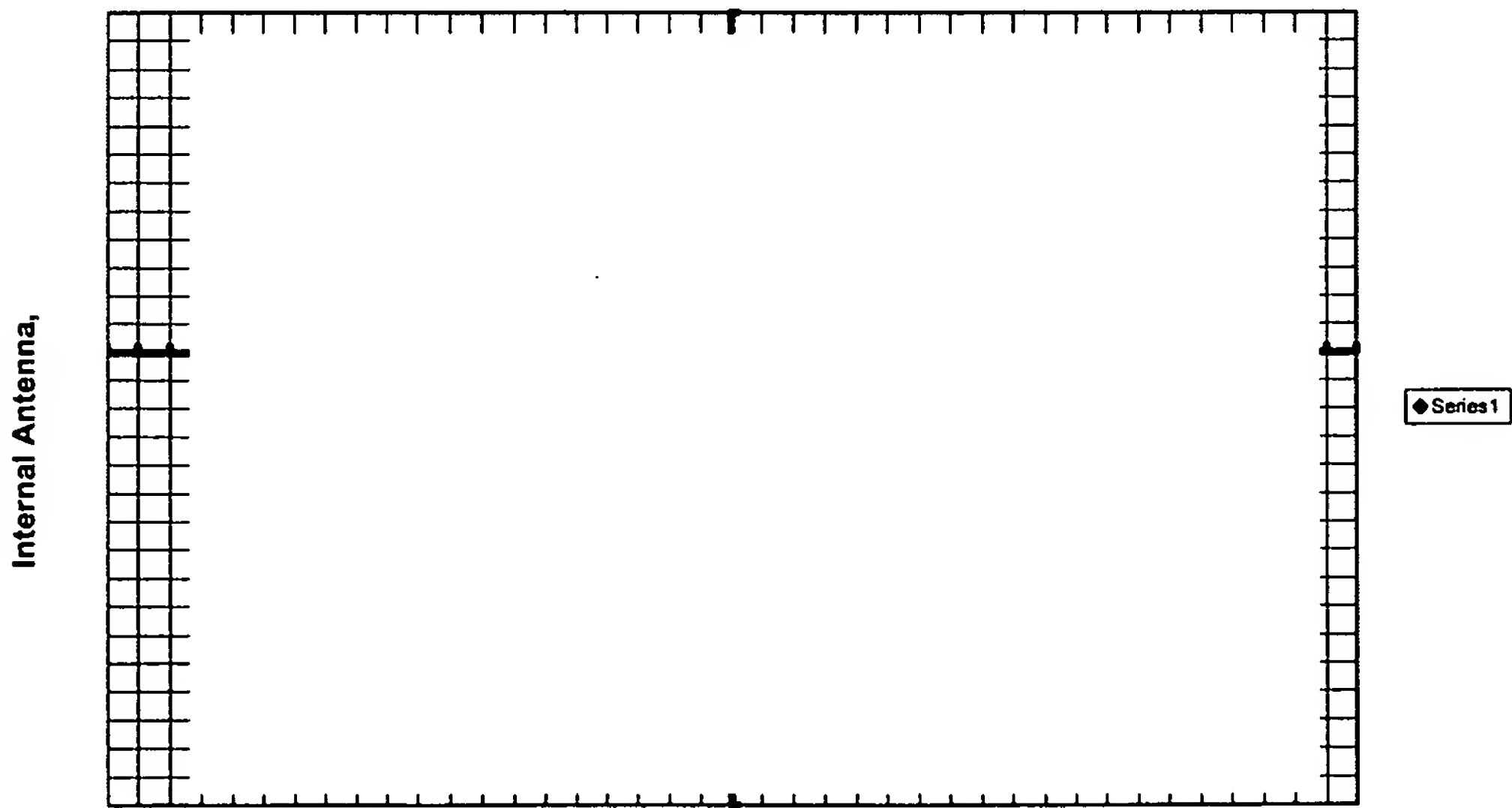

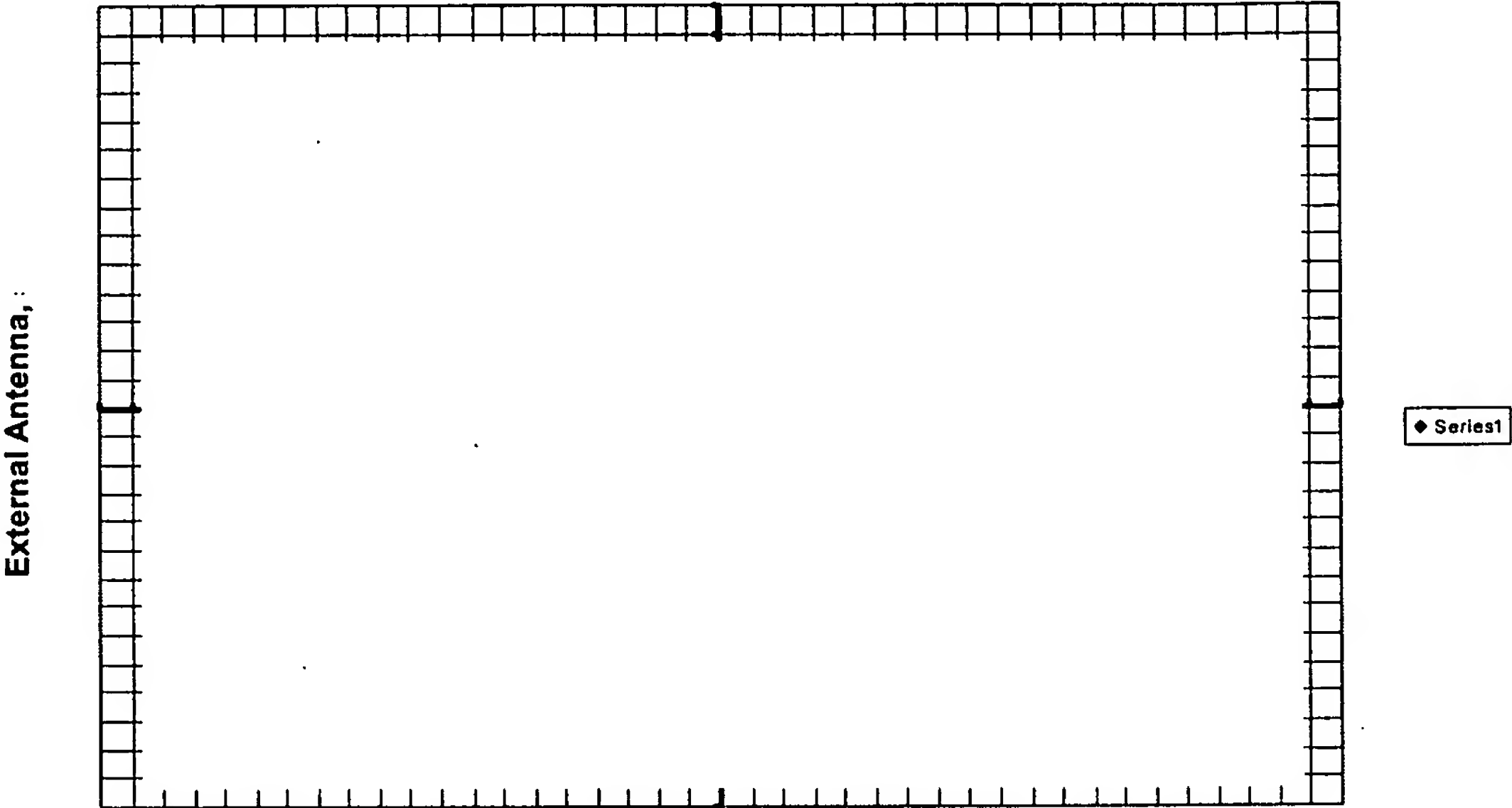


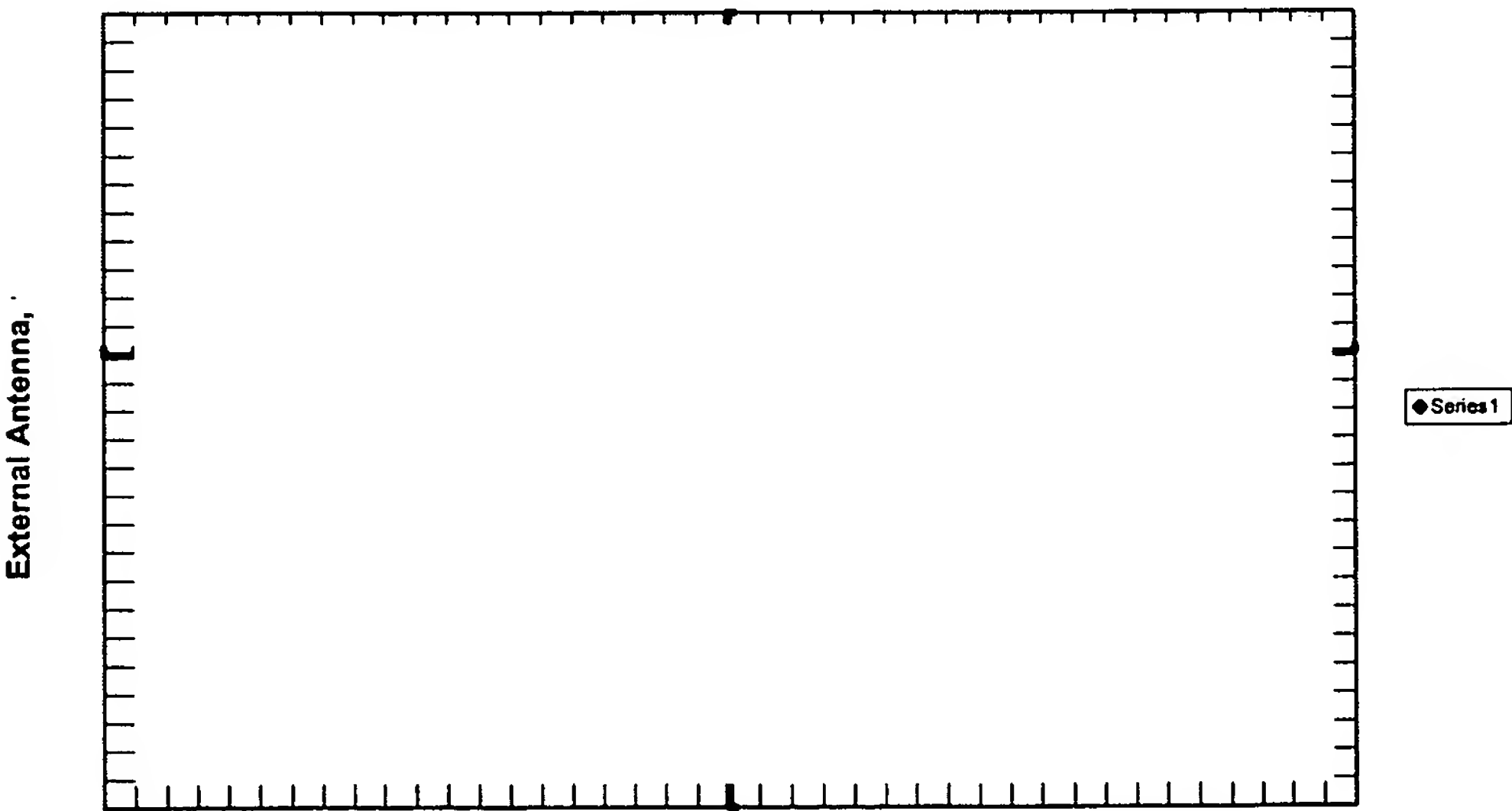
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4.6.1.7.3 External Antenna Map @



4.6.1.7.4 External Antenna @



4.6.1.7.5 Photo of test fixture showing

EXHIBIT B (cont.)



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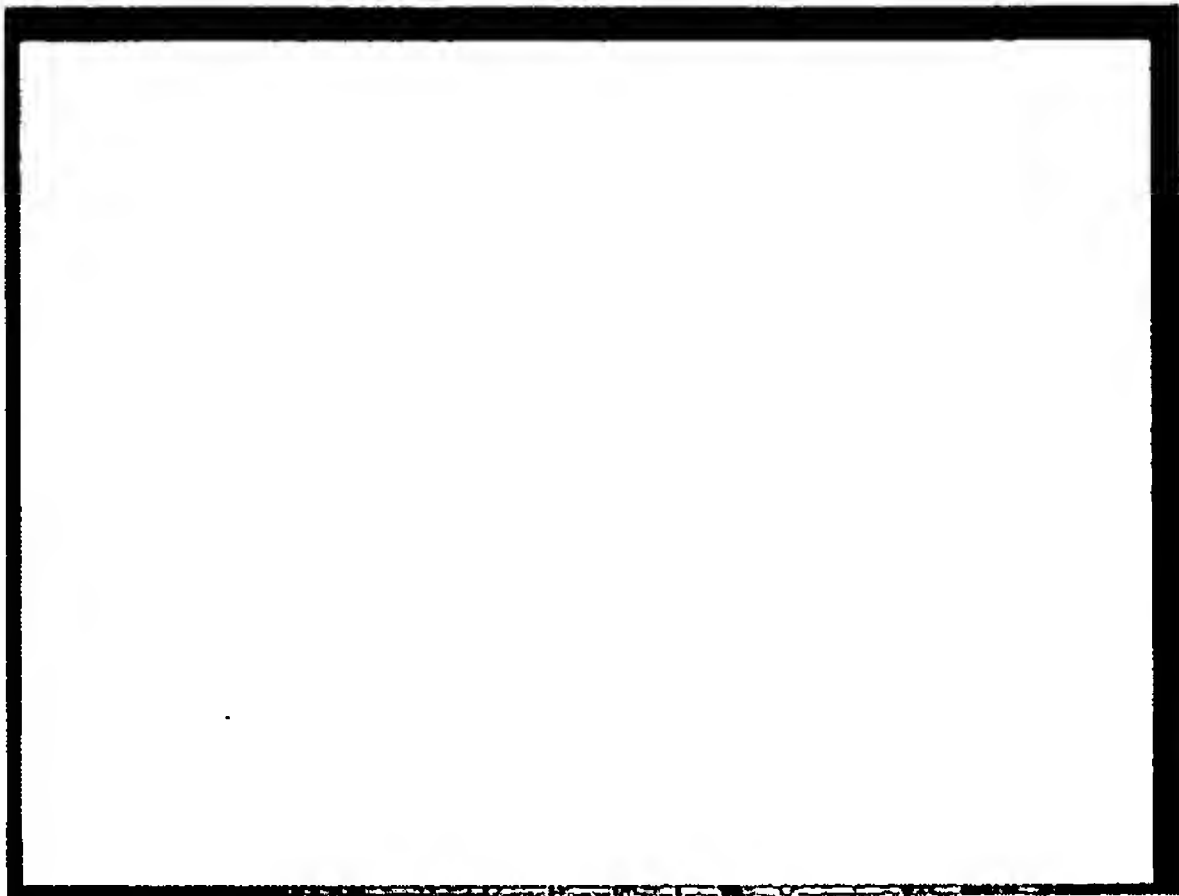
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in this photo.



4.6.1.7.6 Photo of

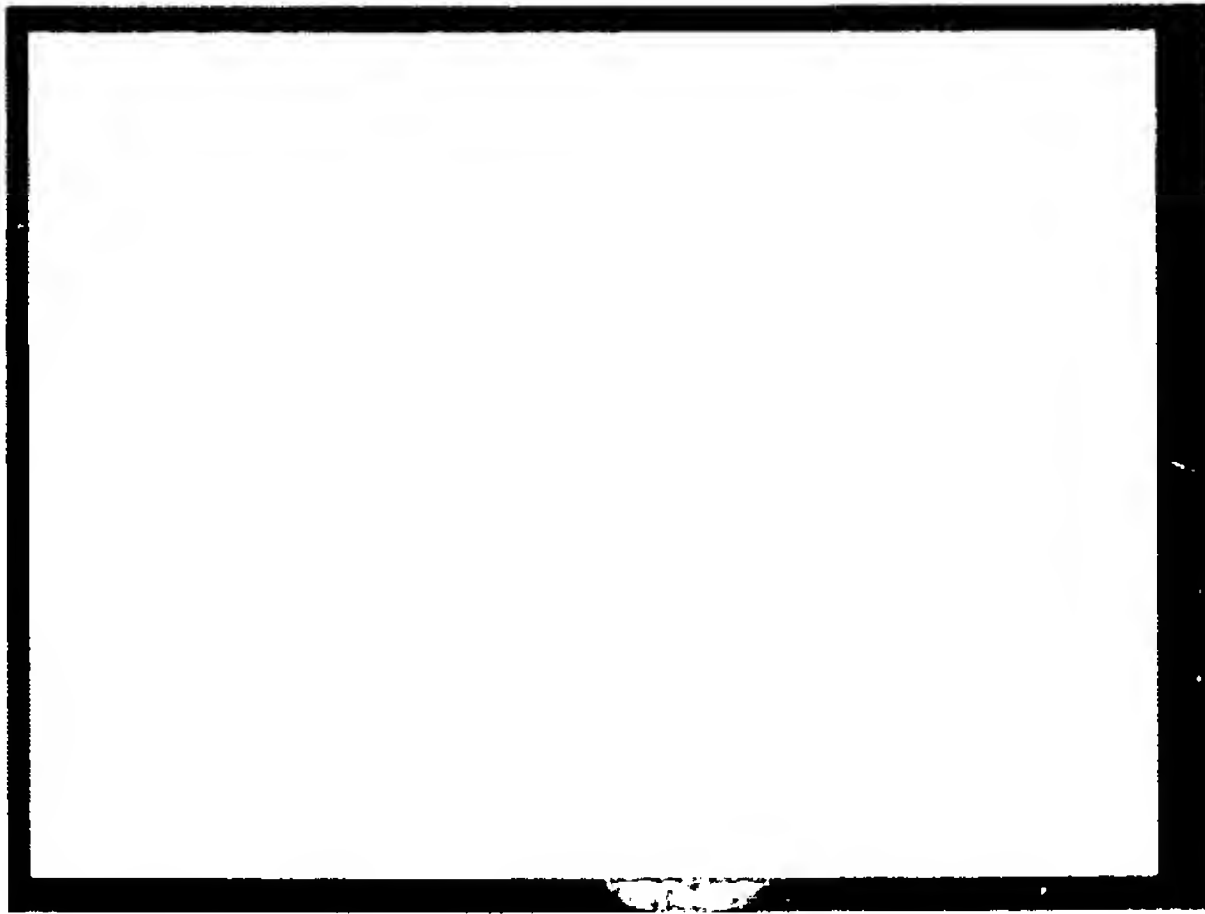



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5 COMPLETION

This paragraph concludes this test specification.

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